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An evaluation on the efficacy and safety of topical oral miconazole nitrate paste in the treatment of oral candidiasis: a randomized, open label, positive controlled, multicenter clinical trial

Registration number:	ChiCTR-TRC-13003935
Date of releasing the registration number:	2013/12/03
Registration Status:	Retrospective registration
Public title:	An evaluation on the efficacy and safety of topical oral miconazole nitrate paste in the treatment of oral candidiasis: a randomized, open label, positive controlled, multicenter clinical trial
Scientific title:	An evaluation on the efficacy and safety of topical oral miconazole nitrate paste in the treatment of oral candidiasis: a randomized, open label, positive controlled, multicenter clinical trial
Secondary ID:	

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Applicant's institution:	Peking University School and Hospital of Stomatology		

Approved by ethic committee:	Yes		
Approved No. of ethic committee:	（2009）伦申第（03）号	Approved file of Ethical Committee:	查看附件View
Name of the ethic committee:	Ethic Committee of Peking University Health Science Center		
Date of approved by ethic committee:	2009/09/15		

Primary sponsor:	Peking University School and Hospital of Stomatology
Primary sponsor's address:	22 Zhongguancun Nandajie, Haidian District, Beijing

Secondary sponsor:	Country:	China	Province:	Guangdong	City:	Shenzhen
	Institution hospital:	JIAN AN PHARMACEUTICAL LIMITED	Address:	No.1016 Shangbu Middle Road, Futian District		

Source(s) of funding:	Hangzhou Tigermed Consulting Co., Ltd
Target disease:	Oral Candidiasis
Target disease code:	
Study type:	Interventional
Study phase:	Phase III
Objectives of Study:	To evaluate the efficacy and safety of topical oral miconazole nitrate paste in the treatment of oral candidiasis.
Study design:	Randomized parallel control
	The inclusion criteria were: 1) age range of 18-70 years; 2) diagnosis of oral candidiasis was established based on clinical manifestation and

Inclusion criteria	laboratory testing (smear test and fungi culture); 3) patients with positive smear test are eligible for instant enrollment; 4) positive rate of fungi culture>80%; 5) negative reaction to pregnancy test in women and willing to take effective method of birth control in the period of trial; 6) voluntarily participating and Informed Consent Form being signed.
Exclusion criteria:	1) diagnosis of cryptococcosis or other systemic fungal infections; 2) a history of a known allergy or intolerance to miconazole nitrate and/or itroconazole; 3) use of rifampicin, rifabutin, isoniazid, phenobarbital, phenytoin, methylprednisolone, carbamazepine, terfenadine, astemizole or cisapride; 4) history of pregnancy or breast-feeding; 5) history of psychological disorder that enable to cooperate; 6) hepaticinsufficiency with serum aminotransferase and total bilirubin levels at 1.5 times the upper limit of normal, or active clinical signs 2 months prior to the trial; 7) serum creatinine levels at 1.5 times the upper limit of normal; 8) history of cardiac insufficiency such as ischemic heart failure; 9) history of hematological diseases; 10) use of systemic or topical antifungal therapy within 2 weeks before study entry (patients received topical treatment with miconazole nitrate or nystatin cream or suppositor remain eligible for enrollment in the study); 11) diagnosis of chronic mucocutaneous candidiasis; 12) hyposalivation related disease or drug-taking; 13) HIV positive; 14) history of participating other clinical trials within 4 weeks before study entry.
Study execute time:	From2009-2-26To 2012-12-5

Interventions:			
Group:	miconazole nitrate group	Sample size:	190
Intervention:	miconazole nitrate sustained release oral paste for topical use once a day	Intervention code:	
Group:	Itroconazole group	Sample size:	190
Intervention:	Itroconazole capsule 100mg QD P.O.	Intervention code:	

Countries of recruitment and research settings:					
Country:	China	Province:	Beijing	City:	
Institution hospital:	Peking University School and Hospital of Stomatology	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Sichuan	City:	Chengdu
Institution hospital:	West China School of Stomatology, Sichuan University	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Jiangsu	City:	Nanjing
Institution hospital:	Institute and Hospital of Dentistry, Nanjing University Medical School	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Hubei	City:	Huhan
Institution hospital:	Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Hubei	City:	Wuhan
Institution hospital:	Wuhan Union Hospital, Huazhong University of Science and Technology	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Shanxi	City:	Xi'an
Institution hospital:	College of Stomatology, the Fourth Military Medical University	Level of the institution:	Grade III		
Country:	China	Province:	Liaoning	City:	Shenyang
Institution hospital:	Hospital of Stomatology, China Medical University	Level of the institution:	Tertiary A hospital		
Country:	China	Province:	Beijng	City:	Beijing
Institution hospital:	Stomatological Hospital, Capital Medical University	Level of the institution:	Tertiary A hospital		

Outcomes:	
Outcome:	Clinical symptoms rating (Pain and burning sensation level)
Outcome:	Clinical sign rating(pseudomenbran and erythema)
Outcome:	candida elimination rate
Outcome:	ECG
Outcome:	CBC
Outcome:	Biochemical Examination

Collecting sample(s) from participants:	Sample Name:	Blood	Tissue:	
	Fate of sample:	Destruction after use	Note:	
	Sample Name:	Saliva	Tissue:	
	Fate of sample:	Destruction after use	Note:	

Recruiting status:	Completed	Participant age:	Min age 19 years Max age 70 years
Randomization Procedure (please state who generates the random number sequence and by what method):	computer	Gender:	Both
Blinding:			
Calculated Results ater the Study Completed:			
Organizer institution (leader institution):			
Data collection Institution:			
Data management Institution:			
Data analysis Institution:			

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